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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,527	12/10/2001	Kiaran McGee	630666.90831	7662

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EXAMINER
FETZNER, TIFFANY A

ART UNIT	PAPER NUMBER
2859	

DATE MAILED: 04/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/016,527	McGee et al.,
Examiner	**Art Unit**
Tiffany Fetzner	2859

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 10, 2001*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-18* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *Dec 10, 2001* is/are a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1-4** are rejected under **35 U.S.C. 102(b)** as being anticipated by **Bernstein et al.**, US patent 5,226,418.

4. With respect to **Claim 1**, **Bernstein et al.**, teaches "A method for producing an image of a subject with a magnetic resonance imaging (MRI)" / nuclear magnetic resonance (NMR) "system", [See **Bernstein et al.**, col. 1 lines 7-12] **Bernstein et al.**, also teaches and suggests "the steps comprising **a)** acquiring a first k-space data set with the MRI / NMR system using a first pulse sequence;" [See col. 4 line 67 through col. 5 line 16; col. 9 lines 26-44] " **b)** acquiring a second k-space data set with the MRI / NMR system using a second pulse sequence which is

different from the first pulse sequence;" [See col. 4 line 67 through col. 5 col. 5 line 16; col. 9 lines 26-44] "**c)** reconstructing first and second complex images of the subject from the respective first and second k-space data sets;" [See col. 9 lines 45-59; col. 10 lines 32-63; col. 11 lines 7-32;] "**d)** calculating a phase difference image from the first and second complex images;" [See col. 11 line 33 through col. 12 line 61] "**e)** calculating a magnitude image from one of said first or second complex images;" [See col. 12 line 43-66; Figure 4] "and **f)** combining the phase difference image with the magnitude image to form the image of the subject." [See col. 12 line 43-66; Figure 4]

5. With respect to **Claim 2**, **Bernstein et al.**, teaches "said first pulse sequence is a spin-echo pulse sequence in which an NMR echo signal is produced after an RF refocusing pulse is produced, [See col. 2 line 52 through col. 3 lines 1-7; col. 10 lines 45-50] **Bernstein et al.**, teaches and suggests that "the second pulse sequence is a gradient-recalled echo pulse sequence in which an NMR echo signal is produced after an RF excitation pulse is produced." [See col. 9 lines 15-25; col. 8 lines 55-60]

6. With respect to **Claim 3**, **Bernstein et al.**, teaches and shows "step c) is performed by performing a complex Fourier transformation of each of the first and second k-space data sets." [See col. 11 lines 7-32; Figure 4]

7. With respect to **Claim 4**, **Bernstein et al.**, teaches and shows "step d) is performed by: I) calculating a first phase image from the first complex image; ii) calculating a second phase image from the second complex image; iii) calculating the phase difference image by computing the phase difference between corresponding pixels in the first and second phase images." [See col 9 line 7 through col. 13 line 15; Figure 4].

8. ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. **Claims 5, 8-12,** and **15-17** are rejected under **35 U.S.C. 103(a)** as being unpatentable over **Bernstein et al.**, US patent 5,226,418 in view of **Zhang et al.**, US patent 6,332,088 B1 issued December 18th 2001, filed November 12th 1998.

12. With respect to **Claims 5, 8, 15, 16** and **17**, **Bernstein et al.**, discloses a method as stated above with respect to claim 1, but lacks directly teaching that with respect to **claims 5**, and **15**, that "step f)" of that method is performed by: employing the phase difference image to locate an implant in the subject; and displaying the location of the implant in the magnitude image." With respect to **claim 8**, **Bernstein et al.**, lacks teaching that "the images are of tissues containing an implant";, "that "step f)" of that method is performed by: "modifying pixels in the magnitude image at the implant location" for **claim 16**, and with respect to **claim 17**, that "step f)" of that

method is performed by: overlaying a graphical representation of the implant at the implant location".

13. However **Zhang et al.**, teaches and suggests these limitations because **Zhang et al.**, teaches the use of an asymmetric magnetic resonance spin-echo sequence for imaging paramagnetic, dimagnetic or ferromagnetic instruments within tissues during interventional MRI procedures, (i.e. with the interventional instrument displayed superimposed on the images of the patient, (i.e. claims 5, 8, 15, 17.) [See col. 3 line 61 through col. 5 line 28] This teaching directly suggests that the implanted interventional object within the patient or subject, is located within the subjects anatomy and that the location in combination with the patient's anatomy is displayed on a display screen. (The examiner notes that conventionally displayed images are magnitude images, unless the reference states otherwise.) [See abstract, col. 1 lines 6-15; col. 1 lines 32-40; col. 3 line 60 through col. 4 line 9; col. 5 lines 22-55] **Zhang et al.**, like **Bernstein et al.**, also teaches analyzing the complex signal magnitude and phase of the resultant MR signal(s), to obtain information about the density of nuclei. Additionally, **Zhang et al.**, teaches using a series of scan sequences with spin-echo or gradient-echo imaging [See col. 4 lines 3-5] which are made at differing phase encoding gradient values to produce image data, [See col. 7 lines 10-12; col. 7 line 24 through col. 8 line 2] and providing improved visualization and predictable control over the apparent size of an imaged instrument. **Zhang et al.**, also teaches a method of modifying pixels/voxels in the resulting magnitude image (i.e. claim 16), through use of an asymmetric spin-echo sequence to exploit the dephasing phenomena and control the apparent size of an imaged instrument at the location that is imaged within a patients imaged tissues. [See col. 3 line 61

through col. 5 line 54; col. 1 lines 6-15; col. 1 lines 33-47; col. 7 lines 15-23; col. 7 line 34 through col. 8 line 2; col. 8 lines 55-64]

14. Therefore, it would have been obvious to one of ordinary skill in the art, at the time that the invention was made, to modify the phase difference method taught by **Bernstein et al.**, to identify the location of an interventional medical instrument or implant as taught by **Zhang et al.**, with both pixel / voxel modification and a graphical representation of the diagnostic instrument or implant displayed in the resulting images because **Zhang et al.**, teaches that analyzing the complex signal magnitude and phase of the resultant MR signal, provides information about nuclei density in the selected and imaged slice, and **Zhang et al.**, exploits the dephasing, or the differences in phases of the pixels/voxels in the resulting images, which are graphically displayed, to control the apparent size of an imaged instrument, or diagnostic tool within a subject's imaged tissues. (I.e. **Zhang et al.**, uses a phase difference method to locate an interventional medical instrument or implant, claims 5, 8, 15.) [See col. 3 line 61 through col. 5 line 54; col. 6 lines 20-23] The method of **Zhang et al.**, suggests a direct application of complex MR magnitude and phase signal analysis, in connection with the ability to locate an interventional device (i.e. an implant) within a subject, while the interventional devices location is displayed with the image of the patients anatomy on the image display. (I.e. **claim 17**) [See col. 3 line 61 through col. 5 line 54; col. 6 lines 20-23; abstract col. 1 lines 6-15; col. 1 lines 32-40].

15. With respect to **Claim 9**, **Bernstein et al.**, teaches and suggests that "step b) is performed by performing a complex Fourier transformation of each of the first and second k-space data sets." [See col. 11 lines 7-32; Figure 4].

16. With respect to **Claim 10, Bernstein et al.**, teaches that "step a) is performed by: I) performing a first pulse sequence to acquire the NMR spin-echo signals; and ii) performing a different pulse sequence to acquire the NMR gradient-recalled signals. [See col. 2 line 52 through col. 3 lines 1-7; col. 10 lines 45-50; col. 9 lines 15-25; col. 8 lines 55-60].

17. With respect to **Claim 11, Bernstein et al.**, teaches that at least "one NMR signal is acquired with each pulse sequence", [See col. 2 line 52 through col. 3 lines 1-7; col. 10 lines 45-50; col. 9 lines 15-25; col. 8 lines 55-60].

18. With respect to **Claim 12, Bernstein et al.**, teaches the limitations that "step c) is performed by: I) calculating a first phase image from the first complex image; ii) calculating a second phase image from the second complex image; iii) calculating the phase difference image by computing the phase difference between corresponding pixels in the first and second phase images", [See col 9 line 7 through col. 13 line 15; Figure 4].

19. **Claims 6, 7, 13, 14,** and **18,** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bernstein et al.**, US patent 5,226,418 in view of **Zhang et al.**, US patent 6,332,088 B1 as applied to **claims 1-5, 8-12,** and **15-17** above, and further in view of alternatively **Slater et al.**, US patent 6,200,258 B1 or **Sliwa et al.,** US patent 6,368,275 B1.

20. With respect to **Claim 6, Bernstein et al.**, lacks directly teaching that "the subject is tissues containing an implant." However **Zhang et al.**, teaches that in interventional applications of MRI it is desirable to visualize the placement of a needle or catheter within tissues. [See **Zhang et al.**, col. 3 lines 61-63, which suggests that the subject is tissues which contain a needle, catheter, or other medical interventional devices which broadly includes implants.] Therefore, it

would have been obvious to one of ordinary skill in the art, at the time that the invention was made, to modify the phase difference method taught by **Bernstein et al.**, to identify the location of an interventional medical instrument or implant as taught by **Zhang et al.**, because **Zhang et al.**, teaches that analyzing the complex signal magnitude and phase of the resultant MR signal, provides information about nuclei density in the selected and imaged slice, and **Zhang et al.**, exploits the dephasing, or the differences in phases of the pixels/voxels in the resulting images, which are graphically displayed, to control the apparent size of an imaged instrument, or diagnostic tool within a subject's imaged tissues.

21. Additionally or alternatively, **Slater et al.**, teaches the limitation that "the subject is tissues containing an implant" [See **Slater et al.**, col. 1 lines 13-30; col. 1 line 67 through col. 2 line 2; col. 4 line 64 through col. 5 line 21, where a titanium brachytherapy seed implant is implanted in tissues in the successful treatment of various types of cancers including prostate cancer.] and **Sliwa et al.,** also teaches that "the subject is tissues containing an implant." [See **Sliwa et al.,** col. 3 lines 1-16; col. 1 lines 8-39; col. 2 lines 19-33; col. 9 lines 12-17; col. 9 lines 42-40; col. 9 lines 58-61].

22. It also would have been obvious to one of ordinary skill in the art, at the time that the invention was made to modify the phase difference method taught by **Bernstein et al.**, to identify the location of an interventional medical instrument or implant as taught by either the **Slater et al.**, or **Sliwa et al.,** references because each of these references (i.e. **Slater et al.**, and **Sliwa et al.,**) teach using MRI / NMR, CAT scan, PET, x-ray, or other conventional diagnostic imaging techniques to directly image their respective novel and / or nonobvious implants or interventional

medical devices within a subject, therefore it would have been obvious to one of ordinary skill in the art, at the time that the invention was made that the phase difference methodology of the teachings of **Bernstein et al**., and **Zhang et al.**, are combinable with the teachings of the **Slater et al.**, and **Sliwa et al.,** references because it is known to use phase difference methodology to locate interventional instruments in MR images, and a brachytherapy seeds are a type of conventional interventional implant. The examiner notes that **Slater et al.**, also teaches that "radioactive therapeutic seeds have been in use for over thirty years" [See **Slater et al.**, col. 2 lines 31-32].

23. With respect to **Claims 7, 13** and corresponding **claim 18** which depends from **claim 15** **Bernstein et al**., and **Zhang et al.**, lack directly teaching that "the tissues include a human prostate and the implant is a brachytherapy seed." However **Slater et al.**, teaches and suggests this limitation. [See **Slater et al.**, col. 1 lines 13-22] Additionally, **Sliwa et al.,** also teaches and suggests this limitation. [See **Sliwa et al.**, col. 3 lines 11-15 where the micro-instrument being a radioactive seed implant directly suggests that "the implant is a brachytherapy seed", and col. 9 lines 58-61 which directly teaches the treatment of human prostate cancer.] It would have been obvious to one of ordinary skill in the art, at the time that the invention was made to modify the teachings of **Bernstein et al**., and **Zhang et al.**, to include imaging human tissue and a brachytherapy seed implant because conventionally, MRI imaging can be performed on any type of human tissue, and brachytherapy seeds are a type or conventionally well known interventional medical devices that are viewable with MRI methods in MRI images.

24. With respect to **Claim 14**, **Bernstein et al**., and **Zhang et al.**, lack teaching that "the implant is formed of titanium". However, this feature is taught and suggested by both the **Slater et al.**, and **Sliwa et al.,** references. [See **Slater et al.**, col. 1 line 67 through col. 2 line 2; col. 4 lines 64-67; col. 5 lines 7-10; and **Sliwa et al.,** col. 3 lines 6-10]. It would have been obvious to one of ordinary skill in the art, at the time that the invention was made to modify the teachings of **Bernstein et al**., and **Zhang et al.**, to include imaging of a titanium because titanium is strong, does not break easily, and is a material from which many conventionally well known interventional medical devices that are viewable with MRI methods in MRI images are made.

25. The **prior art made of record** and not relied upon is considered pertinent to applicant's disclosure.

A) **Darrow et al.**, US patent 5,730,129 which shows another MRI tracking system for locationg an interventional device within a patient, superimposed on a graphical display.

B) **Harvey** US patent 6,275,038 B1 which shows additional phase-difference techniques used with MRI.

Conclusion

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Tiffany Fetzner** whose telephone number is **(703) 305-0430**. The examiner can normally be reached on Monday-Thursday from 7:00am to 4:30pm., and on alternate Friday's from 7:00am to 3:30pm.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Diego Gutierrez**, can be reached on **(703) 308-3875**. The fax phone number for the organization where this application or proceeding is assigned is (703)305-3432 .

28. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0956.

TAF

April 2, 2003

Diego Gutierrez
Supervisory Patent Examiner
Technology Center 2800